

FFW

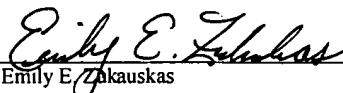
DOCKET NO.: C1037.70042US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Krieg et al.
Serial No.: 10/613,524
Confirmation No.: 4728
Filed: July 3, 2003
For: NUCLEIC ACID COMPOSITIONS FOR STIMULATING IMMUNE RESPONSES
Examiner: Oluwatosin A. Ogunbiyi
Art Unit: 1645

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 5th day of December, 2006.


Emily E. Zilkauskas

MAIL STOP AMENDMENT

Commissioner For Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

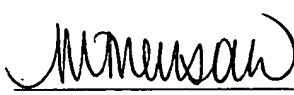
Transmitted herewith are the following documents:

- Information Disclosure Statement
- PTO Form 1449 with cited references
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 646-8000, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,

By: 
Maria A. Trevisan, Reg. No.: 48,207
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
Telephone: (617) 646-8000

Docket No.: C1037.70042US00
Date: December 5, 2006
xNDDx



DOCKET NO.: C1037.70042US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Krieg et al.
Serial No.: 10/613,524
Confirmation No.: 4728
Filed: July 3, 2003
For: NUCLEIC ACID COMPOSITIONS FOR STIMULATING
IMMUNE RESPONSES
Examiner: Oluwatosin A. Ogunbiyi
Art Unit: 1645

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 5th day of December, 2006.

Emily E. Zukauskas
Emily E. Zukauskas

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing of a first Office action on the merits in the above-identified case.

No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified PTO/SB/08). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The Applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application:

<u>Serial No.</u>	<u>Filing Date</u>	<u>Inventor(s)</u>	<u>Docket No.</u>
10/532,746	09-09-2005	Ahluwalia et al.	*C1037.70035US01
11/179,008	07-08-2005	Hartmann et al.	*C1039.70044US02
11/411,975	04-26-2006	Uhlmann et al.	*C1041.70045US01
11/503,377	08-11-2006	Krieg et al.	*C1039.70061US01
11/503,483	08-11-2006	Krieg et al.	*C1039.70048US22
11/507,079	08-18-2006	Krieg et al.	*C1039.70035US04
11/526,197	09-22-2006	Krieg et al.	*C1039.70048US23
11/526,896	09-22-2006	Bratzler et al.	*C1037.70013US03
11/542,845	10-04-2006	Krieg et al.	*C1037.70048US01
11/543,314	10-04-2006	Lipford et al.	*C1041.70036US02
11/595,823	11-10-2006	Wagner et al.	*C1041.70035US01
11/598,207	11-10-2006	Krieg et al.	*C1039.70048US24

*A copy of this reference is not provided as the Office has waived the requirement under 37 C.F.R. 1.98(a)(2)(iii) for submitting a copy of a cited U.S. patent application if it is scanned to the Image File Wrapper system and is available on Private PAIR.

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;

2. The enclosed form PTO-1449 (modified PTO/SB/08) be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

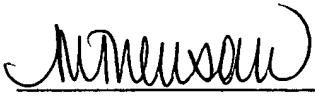
By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his or her own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,

By:



Maria A. Trevisan, Reg. No. 48,207
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
Telephone: (617) 646-8000

Docket No.: C1037.70042US00

Date: December 5, 2006

xNDDx

FORM PTO-1449/A and B (modified PTO/SB/08)		APPLICATION NO.: 10/613,524	ATTY. DOCKET NO.: C1037.70042US00
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		FILING DATE: July 3, 2003	CONFIRMATION NO.: 4728
		APPLICANT: Krieg et al.	
Sheet 1	of 9	GROUP ART UNIT: 1645	EXAMINER: Oluwatosin A. Ogunbiyi

DEC 08 2006

U.S. PATENT DOCUMENTS

Examiner's Initials #	Cite	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A61	6,030,955		Stein et al.	02-29-2000
	A62	6,221,882		Macfarlane	04-24-2001
	A63	6,339,630		Macfarlane	06-04-2002
	A64	6,479,504		Macfarlane et al.	11-12-2002
	A65	6,521,637		Macfarlane	02-18-2003
	A66	6,558,670	B1	Friede et al.	05-06-2003
	A67	6,610,661	B1	Carson et al.	08-26-2003
	A68	6,821,957	B1	Krieg et al.	11-23-2004
	A69	6,943,240		Bauer et al.	09-13-2005
	A70	6,949,520		Hartmann et al.	09-27-2005
	A71	7,001,890		Wagner et al.	02-26-2006
	A72	2002-0192184	A1	Carpentier et al.	12-19-2002
	A73	2003-0232856	A1	Macfarlane	12-18-2003
	A74	2004-0038922	A1	Haensler et al.	02-26-2004
	A75	2004-0047869	A1	Garcon et al.	03-11-2004
	A76	2004-0053880	A1	Krieg	03-18-2004
	A77	2004-0067902	A9	Bratzler et al.	04-08-2004
	A78	2004-0076905	A1	Yagihashi et al.	04-22-2004
	A79	2004-0198680	A1	Krieg	10-07-2004
	A80	2004-0229835	A1	Krieg et al.	11-18-2004
	A81	2004-0234512	A1	Wagner et al.	11-25-2004
	A82	2004-0234960	A1	Olek et al.	11-25-2004
	A83	2004-0235770	A1	Davis et al.	11-25-2004
	A84	2004-0235774	A1	Bratzler et al.	11-25-2004
	A85	2004-0235777	A1	Wagner et al.	11-25-2004
	A86	2004-0235778	A1	Wagner et al.	11-25-2004
	A87	2004-0247662	A1	Dow et al.	12-09-2004
	A88	2004-0266719	A1	McCluskie et al.	12-30-2004
	A89	2005-0004061	A1	Krieg et al.	01-06-2005
	A90	2005-0004062	A1	Krieg et al.	01-06-2005
	A91	2005-0004144	A1	Carson et al.	01-06-2005
	A92	2005-0009774	A1	Krieg et al.	01-13-2005

EXAMINER:

DATE CONSIDERED:

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT			APPLICATION NO.: 10/613,524	ATTY. DOCKET NO.: C1037.70042US00
			FILING DATE: July 3, 2003	CONFIRMATION NO.: 4728
			APPLICANT: Krieg et al.	
			GROUP ART UNIT: 1645	EXAMINER: Oluwatosin A. Ogunbiyi
Sheet	2	of	9	

A93	2005-0013812	A1	Dow et al.	01-20-2005
A94	2005-0019340	A1	Garcon et al.	01-27-2005
A95	2005-0031638	A1	Dalemans et al.	02-10-2005
A96	2005-0032734	A1	Davis et al.	02-10-2005
A97	2005-0032736	A1	Krieg et al.	02-10-2005
A98	2005-0037403	A1	Krieg et al.	02-17-2005
A99	2005-0037985	A1	Krieg et al.	02-17-2005
A100	2005-0038239	A1	Catchpole	02-17-2005
A101	2005-0043529	A1	Davis et al.	02-24-2005
A102	2005-0049215	A1	Krieg et al.	03-03-2005
A103	2005-0049216	A1	Krieg et al.	03-03-2005
A104	2005-0054601	A1	Wagner et al.	03-10-2005
A105	2005-0054602	A1	Krieg et al.	03-10-2005
A106	2005-0059619	A1	Krieg et al.	03-17-2005
A107	2005-0059625	A1	Krieg et al.	03-17-2005
A108	2005-0064401	A1	Olek et al.	03-24-2005
A109	2005-0070491	A1	Krieg et al.	03-31-2005
A110	2005-0075302	A1	Hutcherson et al.	04-07-2005
A111	2005-0100983	A1	Bauer et al.	05-12-2005
A112	2005-0101554	A1	Krieg et al.	05-12-2005
A113	2005-0101557	A1	Krieg et.al.	05-12-2005
A114	2005-0119273	A1	Lipford et al.	06-02-2005
A115	2005-0123523	A1	Krieg et al.	06-09-2005
A116	2005-0130911	A1	Uhlmann et al.	06-16-2005
A117	2005-0148537	A1	Krieg et al.	07-07-2005
A118	2005-0169888	A1	Hartman et al.	08-04-2005
A119	2005-0171047	A1	Krieg et al.	08-04-2005
A120	2005-0181422	A1	Bauer et al.	08-18-2005
A121	2005-0182017	A1	Krieg	08-18-2005
A122	2005-0197314	A1	Krieg et al.	09-08-2005
A123	2005-0215500	A1	Krieg et al.	09-29-2005
A124	2005-0215501	A1	Lipford et al.	09-29-2005
A125	2005-0233995	A1	Krieg et al.	10-20-2005
A126	2005-0233999	A1	Krieg et al.	10-20-2005
A127	2005-0239732	A1	Krieg et al.	10-27-2005
A128	2005-0239733	A1	Jurk et al.	10-27-2005

EXAMINER:	DATE CONSIDERED:
-----------	------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered.
Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08) INFORMATION DISCLOSURE STATEMENT BY APPLICANT			APPLICATION NO.: 10/613,524	ATTY. DOCKET NO.: C1037.70042US00	
			FILING DATE: July 3, 2003	CONFIRMATION NO.: 4728	
			APPLICANT: Krieg et al.		
			GROUP ART UNIT: 1645	EXAMINER: Oluwatosin A. Ogunbiyi	
Sheet	3	of	9		

A129	2005-0239734	A1	Uhlmann et al.	10-27-2005
A130	2005-0239736	A1	Krieg et al.	10-27-2005
A131	2005-0245477	A1	Krieg et al.	11-03-2005
A132	2005-0244379	A1	Krieg et al.	11-03-2005
A133	2005-0244380	A1	Krieg et al.	11-03-2005
A134	2005-0250726	A1	Krieg et al.	11-10-2005
A135	2005-0256073	A1	Lipford et al.	11-17-2005
A136	2005-0267057	A1	Krieg	12-01-2005
A137	2005-0267064	A1	Krieg et al.	12-01-2005
A138	2005-0277604	A1	Krieg et al.	12-15-2005
A139	2005-0277609	A1	Krieg et al.	12-15-2005
A140	2006-0003955	A1	Krieg et al.	01-05-2006
A141	2006-0003962	A1	Ahluwalia et al.	01-05-2006
A142	2006-0019916	A1	Krieg et al.	01-26-2006
A143	2006-0019923	A1	Davis et al.	01-26-2006
A144	2006-0058251	A1	Krieg et al.	03-16-2006
A145	2006-0089326	A1	Krieg et al.	04-27-2006
A146	2006-0094683	A1	Krieg et al.	05-04-2006
A147	2006-0140875	A1	Krieg et al.	06-29-2006
A148	2006-0154890	A1	Bratzler et al.	07-13-2006
A149	2006-0172966	A1	Lipford et al.	08-03-2006
A150	2006-0188913	A1	Krieg et al.	08-24-2006
A151	2006-0211639	A1	Bratzler et al.	09-21-2006
A152	2006-0211644	A1	Krieg et al.	09-21-2006
A153	2006-0229271	A1	Krieg et al.	10-12-2006
A154	2006-0241076	A1	Uhlmann et al.	10-26-2006
A155	2006-0246035	A1	Ahluwalia et al.	11-02-2006

FOREIGN PATENT DOCUMENTS

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			
	B6	EP	0 302 758	A1	New England Medical Center Hospitals, Inc.	02-08-1989	
	B7	EP	0 468 520	A2	Mitsui Toatsu Chemicals, Inc.	01-29-1992	
	B8	WO	96/02555	A1	University of Iowa Research Foundation	02-01-1996	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08)				APPLICATION NO.: 10/613,524	ATTY. DOCKET NO.: C1037.70042US00	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				FILING DATE: July 3, 2003	CONFIRMATION NO.: 4728	
				APPLICANT: Krieg et al.		
Sheet	4	of	9	GROUP ART UNIT: 1645	EXAMINER: Oluwatosin A. Ogunbiyi	

B9	WO	99/56755	A1	University of Iowa Research Foundation	11-11-1999	
B10	WO	00/06588	A1	University of Iowa Research Foundation	02-10-2000	
B11	WO	00/15256	A2	Pasteur Merieux Serums Et Vaccins [FR]	03-23-2000	Abstract
B12	WO	00/54803	A2	Panacea Pharmaceuticals, LLC.	09-21-2000	
B13	WO	00/61151	A2	The Government of the United States of America	10-19-2000	
B14	WO	01/22972	A2	Coley Pharmaceuticals, GmbH	04-05-2001	
B15	WO	01/35991	A2	Dynavax Technologies Corporation	05-25-2001	
B16	WO	01/45750	A1	Regents of the University of California	06-28-2001	
B17	WO	02/28428	A2	Aventis Pasteur [FR]	04-11-2002	Abstract
B18	WO	2004/007743	A2	Coley Pharmaceutical GmbH	01-22-2004	
B19	WO	2004/026888	A2	Coley Pharmaceutical GmbH	04-01-2004	
B20	WO	2004/094671	A2	Coley Pharmaceutical GmbH	11-04-2004	
B21	WO	2005/004910	A2	Intercell Ag	01-20-2005	
B22	WO	2005/023289	A1	Intellectual Property Consulting Incorporated	03-17-2005	Abstract

OTHER ART – NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C1	AGRAWAL et al., Medicinal chemistry and therapeutic potential of CpG DNA. Trends Mol Med. 2002 Mar;8(3):114-21.	
	C2	ASKEW et al., CpG DNA induces maturation of dendritic cells with distinct effects on nascent and recycling MHC-II antigen-processing mechanisms. J Immunol. 2000 Dec 15;165(12):6889-95.	
	C3	AUF et al., Implication of macrophages in tumor rejection induced by CpG-oligodeoxynucleotides without antigen. Clin Cancer Res. 2001 Nov;7(11):3540-3.	
	C4	BALLAS et al., Divergent therapeutic and immunologic effects of oligodeoxynucleotides with distinct CpG motifs. J Immunol. 2001 Nov 1;167(9):4878-86.	
	C5	BARAL et al., Immunostimulatory CpG oligonucleotides enhance the immune response of anti-idiotype vaccine that mimics carcinoembryonic antigen. Cancer Immunol Immunother. 2003 May;52(5):317-27.	
	C6	BITTON et al., Cancer vaccines: a critical review on clinical impact. Curr Opin Mol Ther. 2004 Feb;6(1):17-26. Abstract Only.	
	C7	BLAZAR et al., Synthetic unmethylated cytosine-phosphate-guanosine oligodeoxynucleotides are potent stimulators of antileukemia responses in naive and bone marrow transplant recipients. Blood. 2001 Aug 15;98(4):1217-25.	
	C8	BROIDE et al., DNA-Based immunization for asthma. Int Arch Allergy Immunol. 1999 Feb-Apr;118(2-4):453-6.	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

APPLICATION NO.:	10/613,524	ATTY. DOCKET NO.:	C1037.70042US00
FILING DATE:	July 3, 2003	CONFIRMATION NO.:	4728
APPLICANT:	Krieg et al.		
GROUP ART UNIT:	1645	EXAMINER:	Oluwatosin A. Ogunbiyi

Sheet 5 of 9

C9	BRUNNER et al., Enhanced dendritic cell maturation by TNF-alpha or cytidine-phosphate-guanosine DNA drives T cell activation in vitro and therapeutic anti-tumor immune responses in vivo. <i>J Immunol.</i> 2000 Dec 1;165(11):6278-86.	
C10	CARPENTIER et al., Successful treatment of intracranial gliomas in rat by oligodeoxynucleotides containing CpG motifs. <i>Clin Cancer Res.</i> 2000 Jun;6(6):2469-73.	
C11	CARPENTIER et al., Oligodeoxynucleotides containing CpG motifs can induce rejection of a neuroblastoma in mice. <i>Cancer Res.</i> 1999 Nov 1;59(21):5429-32.	
C12	CHAN et al., CpG-A and CpG-B oligodeoxynucleotides differentially affect the cytokine profile, chemokine receptor expression and T-cell priming function of human plasmacytoid dendritic cells. <i>Blood.</i> 2002;100:50b. Abstract #3666.	
C13	CHATTERJEE et al., Idiotypic antibody immunotherapy of cancer. <i>Cancer Immunol Immunother.</i> 1994 Feb;38(2):75-82.	
C14	CHOI et al., The level of protection against rotavirus shedding in mice following immunization with a chimeric VP6 protein is dependent on the route and the coadministered adjuvant. <i>Vaccine.</i> 2002 Mar 15;20(13-14):1733-40.	
C15	CHU et al., CpG oligodeoxynucleotides act as adjuvants that switch on T helper 1 (Th1) immunity. <i>J Exp Med.</i> 1997 Nov 17;186(10):1623-31.	
C16	COOPER et al., Safety and immunogenicity of CPG 7909 injection as an adjuvant to Fluarix influenza vaccine. <i>Vaccine.</i> 2004 Aug 13;22(23-24):3136-43.	
C17	DAFTARIAN et al., Two distinct pathways of immuno-modulation improve potency of p53 immunization in rejecting established tumors. <i>Cancer Res.</i> 2004 Aug 1;64(15):5407-14.	
C18	DAVILA et al., Generation of antitumor immunity by cytotoxic T lymphocyte epitope peptide vaccination, CpG-oligodeoxynucleotide adjuvant, and CTLA-4 blockade. <i>Cancer Res.</i> 2003 Jun 15;63(12):3281-8.	
C19	DAVILA et al., Repeated administration of cytosine-phosphorothiolated guanine-containing oligonucleotides together with peptide/protein immunization results in enhanced CTL responses with anti-tumor activity. <i>J Immunol.</i> 2000 Jul 1;165(1):539-47.	
C20	DAVIS et al., CpG ODN is safe and highly effective in humans as adjuvant to HBV vaccine: Preliminary results of Phase I trial with CpG ODN 7909. Third Annual Conference on Vaccine Res. 2000. Abstract s25, number 47.	
C21	DE GRUJIL et al., Cancer vaccine strategies get bigger and better. <i>Nat Med.</i> 1999 Oct;5(10):1124-5.	
C22	DONNELLY et al., Cancer vaccine targets leukemia. <i>Nat Med.</i> 2003 Nov;9(11):1354-6.	
C23	EZZELL et al., Cancer "Vaccines": An idea whose time has come? <i>J NIH Research.</i> 1995;7:46-9.	
C24	FILION et al., Development of immunomodulatory six base-length non-CpG motif oligonucleotides for cancer vaccination. <i>Vaccine.</i> 2004 Jun 23;22(19):2480-8.	
C25	FORNI et al., Immunoprevention of cancer: is the time ripe? <i>Cancer Res.</i> 2000 May 15;60(10):2571-5.	
C26	GALLICHAN et al., Intranasal immunization with CpG oligodeoxynucleotides as an adjuvant dramatically increases IgA and protection against herpes simplex virus-2 in the genital tract. <i>J Immunol.</i> 2001 Mar 1;166(5):3451-7.	
C27	GAO et al., Bacterial DNA and lipopolysaccharide induce synergistic production of TNF-alpha through a post-transcriptional mechanism. <i>J Immunol.</i> 2001 Jun 1;166(11):6855-60.	

EXAMINER:

DATE CONSIDERED:

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08)				APPLICATION NO.: 10/613,524	ATTY. DOCKET NO.: C1037.70042US00
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				FILING DATE: July 3, 2003	CONFIRMATION NO.: 4728
				APPLICANT: Krieg et al.	
Sheet	6	of	9	GROUP ART UNIT: 1645	EXAMINER: Oluwatosin A. Ogunbiyi

C28	GARBI et al., CpG motifs as proinflammatory factors render autochthonous tumors permissive for infiltration and destruction. <i>J Immunol.</i> 2004 May;172(10):5861-9.	
C29	GOUTTEFANGEAS et al., Problem solving for tumor immunotherapy. <i>Nat Biotechnol.</i> 2000 May;18(5):491-2.	
C30	GROSSMANN et al., Avoiding tolerance against prostatic antigens with subdominant peptide epitopes. <i>J Immunother.</i> 2001 May-Jun;24(3):237-41.	
C31	HAFNER et al., Antimetastatic effect of CpG DNA mediated by type I IFN. <i>Cancer Res.</i> 2001 Jul 15;61(14):5523-8.	
C32	HARTMANN et al., CpG DNA: a potent signal for growth, activation, and maturation of human dendritic cells. <i>Proc Natl Acad Sci U S A.</i> 1999 Aug 3;96(16):9305-10.	
C33	HEEG et al., CpG DNA as a Th1 trigger. <i>Int Arch Allergy Immunol.</i> 2000 Feb;121(2):87-97.	
C34	JAIN et al., Barriers to drug delivery in solid tumors. <i>Scientific American.</i> 1994; 271:58-65.	
C35	JAKOB et al., Activation of cutaneous dendritic cells by CpG-containing oligodeoxynucleotides: a role for dendritic cells in the augmentation of Th1 responses by immunostimulatory DNA. <i>J Immunol.</i> 1998 Sep 15;161(6):3042-9.	
C36	JAKOB et al., Bacterial DNA and CpG-containing oligodeoxynucleotides activate cutaneous dendritic cells and induce IL-12 production: implications for the augmentation of Th1 responses. <i>Int Arch Allergy Immunol.</i> 1999 Feb-Apr;118(2-4):457-61.	
C37	JUFFERMANS et al., CpG oligodeoxynucleotides enhance host defense during murine tuberculosis. <i>Infect Immun.</i> 2002 Jan;70(1):147-52.	
C38	KATAOKA et al., Antitumor activity of synthetic oligonucleotides with sequences from cDNA encoding proteins of <i>Mycobacterium bovis</i> BCG. <i>Jpn J Cancer Res.</i> 1992 Mar;83(3):244-7.	
C39	KATAOKA et al., Immunotherapeutic potential in guinea-pig tumor model of deoxyribonucleic acid from <i>Mycobacterium bovis</i> BCG complexed with poly-L-lysine and carboxymethylcellulose. <i>Jpn J Med Sci Biol.</i> 1990 Oct;43(5):171-82.	
C40	KLINMAN et al., Immunotherapeutic applications of CpG-containing oligodeoxynucleotides. <i>Drug News Perspect.</i> 2000 Jun;13(5):289-96.	
C41	KLINMAN et al., Immune recognition of foreign DNA: a cure for bioterrorism? <i>Immunity.</i> 1999 Aug;11(2):123-9.	
C42	KRIEG et al., Bacterial DNA or oligonucleotides containing CpG motifs protect mice from lethal L. monocytogenes challenge. 1996 Meeting on Molecular Approaches to the Control of Infectious Diseases. Cold Spring Harbor Laboratory, September 9-13, 1996: 116.	
C43	KRIEG et al., Enhancing vaccines with immune stimulatory CpG DNA. <i>Curr Opin Mol Ther.</i> 2001 Feb;3(1):15-24.	
C44	KRIEG et al., Applications of immune stimulatory CpG DNA for antigen-specific and antigen-nonspecific cancer immunotherapy. <i>Eur J Canc.</i> 1999 Oct; 35/Suppl4:S10. Abstract #14.	
C45	KRIEG et al., Mechanisms and therapeutic applications of immune stimulatory CpG DNA. <i>Pharmacol Ther.</i> 1999 Nov;84(2):113-20.	
C46	KRIEG et al., The CpG motif: Implications for clinical immunology. <i>BioDrugs.</i> 1998 Nov 1;10(5):341-6.	
C47	KRIEG, Immune effects and mechanisms of action of CpG motifs. <i>Vaccine.</i> 2000 Nov 8;19(6):618-22.	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08)			APPLICATION NO.: 10/613,524	ATTY. DOCKET NO.: C1037.70042US00
INFORMATION DISCLOSURE STATEMENT BY APPLICANT			FILING DATE: July 3, 2003	CONFIRMATION NO.: 4728
			APPLICANT: Krieg et al.	
Sheet	7	of	9	GROUP ART UNIT: 1645 EXAMINER: Oluwatosin A. Ogunbiyi

C48	KRIEG, The role of CpG motifs in innate immunity. <i>Curr Opin Immunol.</i> 2000 Feb;12(1):35-43.	
C49	KURAMOTO et al., Induction of T-cell-mediated immunity against MethA fibrosarcoma by intratumoral injections of a bacillus Calmette-Guerin nucleic acid fraction. <i>Cancer Immunol Immunother.</i> 1992;34(5):283-8.	
C50	LEE et al., Immuno-stimulatory effects of bacterial-derived plasmids depend on the nature of the antigen in intramuscular DNA inoculations. <i>Immunology.</i> 1998 Jul;94(3):285-9.	
C51	LEITNER et al., Nucleic acid for the treatment of cancer: genetic vaccines and DNA adjuvants. <i>Curr Pharm Des.</i> 2001 Nov;7(16):1641-67.	
C52	LIANG et al., Activation of human B cells by phosphorothioate oligodeoxynucleotides. <i>J Clin Invest.</i> 1996 Sep 1;98(5):1119-29.	
C53	LIPFORD et al., CpG-containing synthetic oligonucleotides promote B and cytotoxic T cell responses to protein antigen: a new class of vaccine adjuvants. <i>Eur J Immunol.</i> 1997 Sep;27(9):2340-4.	
C54	LIU et al., CpG ODN is an effective adjuvant in immunization with tumor antigen. <i>J Invest Med.</i> 1997 Sept;45(7):333A.	
C55	LIU et al., Immunostimulatory CpG oligodeoxynucleotides enhance the immune response to vaccine strategies involving granulocyte-macrophage colony-stimulating factor. <i>Blood.</i> 1998 Nov 15;92(10):3730-6.	
C56	LONSDORF et al., Intratumor CpG-oligodeoxynucleotide injection induces protective antitumor T cell immunity. <i>J Immunol.</i> 2003 Oct 15;171(8):3941-6.	
C57	MacFARLANE et al., Unmethylated CpG-containing oligodeoxynucleotides inhibit apoptosis in WEHI 231 B lymphocytes induced by several agents: evidence for blockade of apoptosis at a distal signalling step. <i>Immunology.</i> 1997 Aug;91(4):586-93.	
C58	MANEGOLD et al., Addition of PF-3512676 (CpG 7909) to a taxane/platinum regimen for first-line treatment of unresectable non-small cell lung cancer (NSCLC) improves objective response—Phase II clinical trial. Pfizer Poster. 2005. Abstract 1131.	
C59	McCLUSKIE et al., CpG DNA is a potent enhancer of systemic and mucosal immune responses against hepatitis B surface antigen with intranasal administration to mice. <i>J Immunol.</i> 1998 Nov 1;161(9):4463-6.	
C60	McCLUSKIE et al., CpG DNA as mucosal adjuvant. <i>Vaccine.</i> 18: 231-237, 2000.	
C61	McCLUSKIE et al., Oral, intrarectal and intranasal immunizations using CpG and non-CpG oligodeoxynucleotides as adjuvants. <i>Vaccine.</i> 2000 Oct 15;19(4-5):413-22.	
C62	McCLUSKIE et al., CpG DNA is an effective oral adjuvant to protein antigens in mice. <i>Vaccine.</i> 2000 Nov 22;19(7-8):950-7.	
C63	McCLUSKIE et al., The potential of oligodeoxynucleotides as mucosal and parenteral adjuvants. <i>Vaccine.</i> 2001 Mar 21;19(17-19):2657-60.	
C64	MICONNET et al., CpG are efficient adjuvants for specific CTL induction against tumor antigen-derived peptide. <i>J Immunol.</i> 2002 Feb 1;168(3):1212-8.	
C65	MILAS et al., CpG oligodeoxynucleotide enhances tumor response to radiation. <i>Cancer Res.</i> 2004 Aug 1;64(15):5074-7.	
C66	MUTWIRI et al., Biological activity of immunostimulatory CpG DNA motifs in domestic animals. <i>Vet Immunol Immunopathol.</i> 2003 Jan 30;91(2):89-103.	

EXAMINER:	DATE CONSIDERED:
-----------	------------------

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

APPLICATION NO.:	10/613,524	ATTY. DOCKET NO.:	C1037.70042US00
FILING DATE:	July 3, 2003	CONFIRMATION NO.:	4728
APPLICANT:	Krieg et al.		
GROUP ART UNIT:	1645	EXAMINER:	Oluwatosin A. Ogunbiyi

Sheet

8 of 9

C67	MUTWIRI et al., Strategies for enhancing the immunostimulatory effects of CpG oligodeoxynucleotides. <i>J Control Release</i> . 2004 May 31;97(1):1-17.	
C68	NINALGA et al., CpG oligonucleotide therapy cures subcutaneous and orthotopic tumors and evokes protective immunity in murine bladder cancer. <i>J Immunother</i> . 2005 Jan-Feb;28(1):20-7.	
C69	O'HAGAN et al., Recent developments in adjuvants for vaccines against infectious diseases. <i>Biomol Eng</i> . 2001 Oct 15;18(3):69-85. Abstract only.	
C70	PAUL et al., Technology evaluation: CpG-7909, Coley. <i>Curr Opin Mol Ther</i> . 2003 Oct;5(5):553-9. Abstract Only.	
C71	PAVLICK et al., Novel therapeutic agents under investigation for malignant melanoma. <i>Expert Opin Investig Drugs</i> . 2003 Sep;12(9):1545-58.	
C72	PISETSKY et al., The immunologic properties of DNA. <i>J Immunol</i> . 1996 Jan 15;156(2):421-3.	
C73	RAY et al., Oral pretreatment of mice with immunostimulatory CpG DNA induces reduced susceptibility to <i>Listeria monocytogenes</i> . <i>Experimental Biology</i> 2001. Orlando, Florida, USA. March 31-April 4, 2001. Abstracts, part II. <i>FASEB J</i> . 2001 Mar 8;15(5):A1007.	
C74	REVAZ et al., The importance of mucosal immunity in defense against epithelial cancers. <i>Curr Opin Immunol</i> . 2005 Apr;17(2):175-9.	
C75	ROCHLITZ et al., Gene therapy of cancer. <i>Swiss Med Wkly</i> . 2001 Jan 12;131(1-2):4-9.	
C76	SCHNEEBERGER et al., CpG motifs are efficient adjuvants for DNA cancer vaccines. <i>J Invest Dermatol</i> . 2004 Aug;123(2):371-9.	
C77	SPEISER et al., Rapid and strong human CD8+ T cell responses to vaccination with peptide, IFA, and CpG oligodeoxynucleotide 7909. <i>J Clin Invest</i> . 2005 Mar;115(3):739-46.	
C78	STERN et al., Vaccination with tumor peptide in CpG adjuvant protects via IFN-gamma-dependent CD4 cell immunity. <i>J Immunol</i> . 2002 Jun 15;168(12):6099-105.	
C79	TAKESHITA et al., Signal transduction pathways mediated by the interaction of CpG DNA with Toll-like receptor 9. <i>Semin Immunol</i> . 2004 Feb;16(1):17-22.	
C80	TOKUNAGA et al., A synthetic single-stranded DNA, poly(dG,dC), induces interferon-alpha/beta and -gamma, augments natural killer activity, and suppresses tumor growth. <i>Jpn J Cancer Res</i> . 1988 Jun;79(6):682-6.	
C81	TORTORA et al., Oral antisense that targets protein kinase A cooperates with taxol and inhibits tumor growth, angiogenesis, and growth factor production. <i>Clin Cancer Res</i> . 2000 Jun;6(6):2506-12.	
C82	VAN OJIK et al., Phase I/II study with CpG 7909 as adjuvant to vaccination with MAGE-3 protein in patients with MAGE-3 positive tumors. <i>Ann Oncol</i> . 2003;13:157. Abstract 579O.	
C83	VERMA et al., Gene therapy—promises, problems, and prospects. <i>Nature</i> . 1997 Sep 18;389:239-42.	
C84	VICARI et al., Reversal of tumor-induced dendritic cell paralysis by CpG immunostimulatory oligonucleotide and anti-interleukin 10 receptor antibody. <i>J Exp Med</i> . 2002 Aug 19;196(4):541-9.	
C85	VILE et al., Cancer gene therapy: hard lessons and new courses. <i>Gene Ther</i> . 2000 Jan;7(1):2-8.	
C86	WAGNER et al., CpG motifs are efficient adjuvants for genetic vaccines to induce antigen-specific protective anti-tumor T cell responses. 2000;203:429. Abstract R46.	
C87	WANG et al., CpG oligodeoxynucleotides inhibit tumor growth and reverse the immunosuppression caused by the therapy with 5-fluorouracil in murine hepatoma. <i>World J Gastroenterol</i> . 2005 Feb 28;11(8):1220-4.	

EXAMINER:

DATE CONSIDERED:

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Sheet 9 of 9

APPLICATION NO.:	10/613,524	ATTY. DOCKET NO.:	C1037.70042US00
FILING DATE:	July 3, 2003	CONFIRMATION NO.:	4728
APPLICANT:	Krieg et al.		
GROUP ART UNIT:	1645	EXAMINER:	Oluwatosin A. Ogunbiyi

C88	WARREN et al., CpG oligodeoxynucleotides enhance monoclonal antibody therapy of a murine lymphoma. Clin Lymphoma. 2000 Jun;1(1):57-61.	
C89	WEERATNA et al., CpG ODN can re-direct the Th bias of established Th2 immune responses in adult and young mice. FEMS Immunol Med Microbiol. 2001 Dec;32(1):65-71.	
C90	WEIGEL et al., Dendritic cell (DC)/AML hybrid vaccine administered with CpG oligodeoxynucleotide adjuvant provides protective anti-tumor effects. Proceedings of the American Association for Cancer Research. 2003 Jul;44(2);394-5. Abstract #1992.	
C91	WEINER et al., Immunostimulatory oligodeoxynucleotides containing the CpG motif are effective as immune adjuvants in tumor antigen immunization. Proc Natl Acad Sci U S A. 1997 Sep 30;94(20):10833-7.	
C92	WEINER et al., The immunobiology and clinical potential of immunostimulatory CpG oligodeoxynucleotides. J Leukoc Biol. 2000 Oct;68(4):455-63.	
C93	WERNETTE et al., CpG oligodeoxynucleotides stimulate canine and feline immune cell proliferation. Vet Immunol Immunopathol. 2002 Jan 15;84(3-4):223-36.	
C94	WOOLDRIDGE et al., CpG DNA and cancer immunotherapy: orchestrating the antitumor immune response. Curr Opin Oncol. 2003 Nov;15(6):440-5.	

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. ___, filed ___, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE – No copies of U.S. patents, published U.S. patent applications, or pending, unpublished patent applications stored in the USPTO's Image File Wrapper (IFW) system, are included. See 37 CFR §1.98 and 1287OG163. Copies of all other patent(s), publication(s), unpublished, pending U.S. patent applications, or other information listed are provided as required by 37 CFR §1.98 unless 1) such copies were provided in an IDS in an earlier application that complies with 37 CFR §1.98, and 2) the earlier application is relied upon for an earlier filing date under 35 U.S.C. §120.]

EXAMINER:	DATE CONSIDERED:
-----------	------------------

[#] EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.